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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,392	01/13/2006	Stephan Soyka	65084.000012	2846
21967 7590 08/04/2009 HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109				
EXAMINER				
PAGE, BRENT T				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,392

Applicant(s)

SOYKA ET AL.

Examiner

BRENT PAGE

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date 11/20/05.
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I and species Ib in the reply filed on 05/14/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, the restriction requirement is hereby made FINAL.

Claim 16 is withdrawn by the Examiner as being drawn to non-elected subject matter. Claims 1-14 and 17-18 are examined herein on the merits.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. There is an embedded hyperlink in paragraph 18 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to multitudes of unspecified genetic modifications and foreign nucleic acids that would lead to a reduction in the expression of the R1 protein.

In contrast the specification only describes the use of sequences from the R1 gene itself for reducing the expression of the R1 gene. There are literally thousands of genes that could potentially affect the expression of the R1 gene. The specification does not contain working examples of genes other than the R1 gene that could be disrupted, modified or transformed into the plant that would reduce the expression of the R1 gene. The specification also does not describe which structural features or enzymatic properties would need to be present in genes other than R1 in order for the reduction in R1 to result from their inclusion as a foreign nucleic acid molecule.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed

genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description

Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites the limitation "said pre-cooked meals" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1, from which claim 17 depends, does not recite "pre-cooked meals". It is unclear how claim 17 would further limit claim 1, and the claim is therefore not able to be examined as currently written.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 10-14 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonnewald (US20020019998) in view of Walsh et al (WO9740707).

The claims are drawn to a process for reducing acrylamide content of heat-treated foods comprising selecting plant material with a reduced content of soluble sugars compared to conventional plant material, processing plant material and heat treating the food, wherein the acrylamide content is reduced by at least 15%, at least 30%, and wherein the heat treatment is carried out at temperatures of at least 100 degrees Celsius, wherein the foods include potato chips, french fries, or parfried potato chips, wherein the plant material is genetically modified, and wherein the plant material originates from potato.

Sonnenwald teaches the genetic modification of potato plants by reducing the expression of the sucrose-phosphate synthase gene (SPS) by anti-sense constructs (see claims Examples 3 and 4, for example) and specifically teaches that the utility of a such an invention is the reduction in soluble sugars that lead to negative effects due to the Maillard reaction for preparing fries and crisps from potato (see paragraph 11 of the specification, for example).

Sonnenwald does not specifically teach the heat treatment of the resulting potato plants for the production of food or the reduction in acrylamide content.

Walsh et al teach the heat-treatment of potato crisps for the production of food, wherein the temperatures are above 100 degrees Celsius (see claim 1 wherein the range of temperature is 132-196 degrees Celsius, for example).

Given the state of the art and the disclosures by Sonnenwald and Walsh et al, it would have been obvious to one of ordinary skill in the art to select the plant material of the transgenic plants taught by Sonnenwald to produce the par-fried potato strips in the

method taught by Walsh et al to avoid the deleterious effects of the Maillard reaction as taught by and evidenced by Sonnewald above. One would have been motivated to do so based on the disclosure by Sonnewald. The specific reductions in acrylamide content would naturally follow from the reduced amount of sugar taught by Sonnewald.

Claims 1-14 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonnewald (US20020019998) in view of Frohberg (US Patent 6521816, filed 11/09/1999) and further, in view of Walsh et al (WO9740707).

The claims teach the method described above wherein the plant with the genetic modification results in the reduction of the expression of the R1 gene.

Sonnewald teaches the genetic modification of potato plants by reducing the expression of the sucrose-phosphate synthase gene (SPS) by anti-sense constructs (see claims Examples 3 and 4, for example) and specifically teaches that the utility of a such an invention is the reduction in soluble sugars that lead to negative effects due to the Maillard reaction for preparing fries and crisps from potato (see paragraph 11 of the specification, for example).

Sonnewald does not specifically teach the heat treatment of the resulting potato plants for the production of food or the reduction in acrylamide content, nor does Sonnewald teach the reduction in expression of the R1 gene in potato.

Walsh et al teach the heat-treatment of potato crisps for the production of food, wherein the temperatures are above 100 degrees Celsius (see claim 1 wherein the range of temperature is 132-196 degrees Celsius, for example).

Frohberg teaches the transformation of potato plants with a vector comprising DNA encoding the R1 protein wherein the expression of R1 is reduced relative to non transformed plants (see claims 1-8 and 22-23, for example) and that cold sweetening leads to the reduction in sugars in the resulting plant material (see 4th paragraph under Background of invention, for example).

Given the state of the art and the disclosures by Sonnewald, Frohberg and Walsh et al, it would have been obvious to one of ordinary skill in the art to select the plant material of the transgenic plants taught by Frohberg to produce the par-fried potato strips in the method taught by Walsh et al to avoid the deleterious effects of the Maillard reaction as taught by and evidenced by Sonnewald above. One would have been motivated to do so based on the disclosure by Sonnewald. The specific reductions in acrylamide content would naturally follow from the reduced amount of sugar taught by Frohberg.

No claims are free of the prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Anne Marie Grunberg/
Supervisory Patent Examiner, Art Unit 1638